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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,240

12/21/2005

Neil Joseph Atkin

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CHIEF PATENT COUNSEL
SMITH & NEPHEW, INC.
1450 BROOKS ROAD
MEMPHIS, TN 38116

EXAMINER

BUIE, NICOLE M

ART UNIT

PAPER NUMBER

1796

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,240	Applicant(s) ATKIN ET AL.	
	Examiner NICOLE M. BUIE	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060821</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Schoenberg (US 4,182,823).

Regarding claims 1, 2, and 5, Schoenberg discloses an adhesive comprising a cyanoacrylate (Abstract, C1/L8-12) in combination with an angiogenic factor (i.e. cellulose acetate butyrate) (C8/L30-51).

Regarding claims 8 and 9, Schoenberg discloses an adhesive wherein the cyanoacrylate is alkyl 2-cyanoacrylate, wherein an alkyl group having 1 to 10 carbon atoms or alkenyl 2-cyanoacrylate (C2/L29-39).

Regarding claim 10, Schoenberg discloses an adhesive wherein the cyanoacrylate is methyl 2-cyanoacrylate or ethyl 2-cyanoacrylate (C7/L50-63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1, 6, and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacPhee et al. (US 6,197,325) in view of Shalaby (US 6,299,631). *This is an alternative rejection of claim(s) 1 above to meet the limitations of angiogenic factor.*

Regarding claim 1, MacPhee et al. discloses a tissue adhesive comprising an angiogenic factor (i.e. tributyrin) (C40/L24-31).

However, MacPhee et al. does not disclose a cyanoacrylate. Shalaby teaches a cyanoacrylate in a tissue adhesive composition (C2/L30-49). MacPhee et al. and Shalaby are analogous art concerned with the same field of endeavor, namely tissue adhesives for tissues, such as muscles. It would have been obvious to one of ordinary skill in the art at the time of invention to use cyanoacrylate of Shalaby in an adhesive of MacPhee et al., and the motivation to do so would have been as Shalaby suggests to use an adhesive that bonds rapidly to tissues and form strong adhesive joints (C2/L30-31).

Regarding claim(s) 11 and 12, MacPhee et al. does not disclose a tissue adhesive that has an adhesive strength of at least 0.05 Mpa. The Office realizes that all of the claimed effects

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or physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients. Therefore, the claimed effects and physical properties, i.e. adhesive strength would implicitly be achieved by a composition with all the claimed ingredients. If it is the applicant's position that this would not be the case: (1) evidence would need to be provided to support the applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties with only the claimed ingredients.

Regarding claim(s) 13-17, MacPhee et al. does not disclose amount of the release of an angiogenic factor or amount of angiogenic factor in an adhesive. As the rate of preventing hyperproliferation of muscle tissue is variable that can be modified by adjusting said amount of angiogenic factor (C40/L23-31), the precise amount of the release of an angiogenic factor and amount of angiogenic factor in an adhesive would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, amount of the release of an angiogenic factor and amount of angiogenic factor in an adhesive, and the motivation to do so would have been to obtain desired rate of preventing hyperproliferation of muscle tissue (*In re Boesch*, 617 F .2d. 272,205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05.

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Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacPhee et al. (US 6,197,325) in view of Shalaby (US 6,299,631) as applied to claim 1 above, and further in view of Toscani et al., *J. Biol. Chem.* 1990, 2655, 5722.

Regarding claims 3 and 4, modified MacPhee discloses an adhesive as shown above in claim 1 above.

MacPhee et al. does not disclose an adhesive wherein the angiogenic factor is a butyric acid salt. Toscani et al. teaches sodium butyrate (Abstract). MacPhee et al. and Toscani et al. are analogous art concerned with the same technical difficulty, namely butyric acids. It would have been obvious to one of ordinary skill in the art at the time of invention to use sodium butyrate of Toscani et al. in an adhesive of MacPhee et al., and the motivation to do so would have been as MacPhee et al. suggests to choose a drug which prevents smooth muscle cell hyperproliferation with extremely low toxicity and does not induce cell damage (C40/L15-23).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scarborough (US 2001/0014831). *This is an alternative rejection of claim(s) 1 above to meet the limitations of angiogenic factor.*

Regarding claim 1, Scarborough discloses a composition comprising a cyanoacrylate in combination with an angiogenic factor (i.e. polyhydroxybutyrate) [0042].

However, Scarborough does not disclose cyanoacrylate and polyhydroxybutyrate together. Since both cyanoacrylate and polyhydroxybutyrate are taught by Scarborough as binders, it is well settled to use a combination of them as *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA 1980). i.e., it is well settled that is a *prima facie* obvious to combine two

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ingredients each of which is taught by the prior art to be useful for the same purpose. See MPEP § 2144.06.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scarborough (US 2001/0014831) as applied to claim 1 above, and evidenced by Justin (US 2001/0037113).

Regarding claim 7, Scarborough discloses a composition as shown above in claim 1. As shown above, Scarborough discloses polyhydroxybutyrate which is a biodegradable polymer which is able to degrade into hydroxybutyrate as evidenced by Justin [0035], objective to evidence to the contrary. Therefore, after degradation polyhydroxybutyrate will break up into its monomeric units and other units.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE M. BUIE whose telephone number is (571)270-3879. The examiner can normally be reached on Monday-Thursday with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571)272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo, Ph.D./
Supervisory Patent Examiner, Art Unit 1796
15-Sep-08

/N. M. B./
Examiner, Art Unit 1796
9/4/2008